

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

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[Docket No. 98N-0335]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Good Laboratory Practices (GLP) Regulations for Nonclinical Studies****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Good Laboratory Practices (GLP) Regulations for Nonclinical Studies, 21 CFR Part 58—  
(OMB Control Number 0910-0119—Extension)**

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOP's), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOP's; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under the GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities,

e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts on-site audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

In the **Federal Register** of June 10, 1998 (63 FR 31786), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section     | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 58.35(b)(7)        | 400                | 60.25                         | 24,100                 | 1                  | 24,100      |
| 58.185             | 400                | 60.25                         | 24,100                 | 27.65              | 666,400     |
| Total burden hours |                    |                               |                        |                    | 690,500     |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section                | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|-------------------------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 58.29(b)                      | 400                  | 20                                 | 8,000                | .21                    | 1,700       |
| 58.35(b)(1) to (b)(6) and (c) | 400                  | 270.76                             | 108,400              | 3.36                   | 363,900     |
| 58.63(b) and (c)              | 400                  | 60                                 | 24,000               | .09                    | 2,200       |
| 58.81(a) to (c)               | 400                  | 301.8                              | 120,000              | .14                    | 16,800      |
| 58.90(c) and (g)              | 400                  | 62.7                               | 25,000               | .13                    | 3,200       |
| 58.105(a) and (b)             | 400                  | 5                                  | 2,000                | 11.8                   | 23,600      |
| 58.107(d)                     | 400                  | 1                                  | 400                  | 4.25                   | 1,700       |
| 58.113(a)                     | 400                  | 15.33                              | 6,132                | 6.8                    | 41,700      |
| 58.120                        | 400                  | 15.38                              | 6,160                | 32.7                   | 201,200     |
| 58.195                        | 400                  | 251.5                              | 100,000              | 3.9                    | 392,400     |
| Total                         |                      |                                    |                      |                        | 1,048,400   |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 17, 1998

September 17, 1998

William K. Hubbard  
Associate Commissioner for Policy Coordination

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*Nisa Bowles*